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ETHICON, INC., and
JOHNSON & JOHNSON

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

JULIE CRUZ and RAY CRUZ,

Plaintiffs,

v.

JOHNSON & JOHNSON, INC.;
ETHICON, INC.; and COLOPLAST
CORP.,

Defendants.

CASE NO.: 8:18-cv-01539-JVS-JDE

**ANSWER AND DEFENSES OF
DEFENDANT JOHNSON & JOHNSON
TO PLAINTIFFS' FIRST AMENDED
COMPLAINT; DEMAND FOR JURY
TRIAL**

The Honorable James V. Selna
Courtroom: 10C (Santa Ana)

Defendant Johnson & Johnson¹ by and through its attorneys, responds to
Plaintiffs' Complaint ("Complaint") as follows.

RESPONSE TO "NATURE OF ACTION"²

1. Johnson & Johnson lacks sufficient knowledge or information to know
whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products; therefore,

¹ Johnson & Johnson is incorrectly identified in the caption of Plaintiffs' Complaint. "Johnson & Johnson, Inc." is a misnomer and the correct corporate name of the defendant referred to as "Johnson & Johnson, Inc." is Johnson & Johnson. There is no corporate entity named "Johnson & Johnson, Inc." but Johnson and Johnson will hereby answer the allegations in the Complaint.

² The repetition of the Complaint's subheadings is done solely for organizational purposes and is not an admission as to their truth.

1 Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining
2 allegations contained in Paragraph 1 of Plaintiffs' Complaint.

3 **RESPONSE TO "PARTIES"**

4 2. Johnson & Johnson is without sufficient knowledge or information so as to
5 form a belief as to the truth of the allegations contained in the first sentence of Paragraph
6 2 of Plaintiffs' Complaint, and, therefore, Johnson & Johnson denies those allegations.
7 Johnson & Johnson denies the remaining allegations contained in Paragraph 2 of
8 Plaintiffs' Complaint.

9 3. Johnson & Johnson admits that it is a New Jersey corporation with its
10 principal place of business located at One Johnson & Johnson Plaza, New Brunswick,
11 New Jersey, and admits that its website speaks for itself. Johnson & Johnson further
12 admits that Ethicon, Inc. developed, manufactured, tested, marketed, promoted,
13 distributed and sold certain pelvic mesh products for uses consistent with the packaging
14 and labeling. Johnson & Johnson does not develop, manufacture, test, market, promote,
15 distribute or sell any product. Johnson & Johnson denies the remaining allegations
16 contained in Paragraph 3 of Plaintiffs' Complaint.

17 4. Johnson & Johnson admits that Ethicon, Inc. is a New Jersey corporation
18 with its principal place of business in Somerville, New Jersey, and that it is a subsidiary
19 of Johnson & Johnson. Johnson & Johnson denies the remaining allegations contained in
20 Paragraph 4 of Plaintiffs' Complaint.

21 5. Paragraph 5 of Plaintiffs' Complaint makes no allegations against Johnson
22 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
23 required, Johnson & Johnson is without sufficient knowledge or information so as to
24 form a belief as to the truth of the allegations contained in Paragraph 5 of Plaintiffs'
25 Complaint, and, therefore, denies those allegations.

26 **RESPONSE TO "JURISDICTION AND VENUE"**

27 6. Paragraph 6 of Plaintiffs' Complaint states a legal conclusion and requires
28 no response by Johnson & Johnson. To the extent a response is required, Johnson &

1 Johnson is without sufficient knowledge or information so as to form a belief as to the
2 truth of the allegations contained in Paragraph 6 of Plaintiffs' Complaint, and, therefore,
3 denies those factual allegations and legal conclusion.

4 7. The first sentence of Paragraph 7 of Plaintiffs' Complaint states a legal
5 conclusion and requires no response by Johnson & Johnson. To the extent a response is
6 required, Johnson & Johnson is without sufficient knowledge or information to form a
7 belief as to the truth of the allegations contained in the first sentence of Paragraph 7, and,
8 therefore, denies those allegations. As to the second sentence of Paragraph 7, Johnson &
9 Johnson admits only that Ethicon, Inc. sold certain pelvic mesh products for uses
10 consistent with the packaging and labeling, and that they have been available for
11 purchase in the State of California. Johnson & Johnson does not sell any product.
12 Johnson & Johnson denies the remaining allegations contained in Paragraph 7 of
13 Plaintiffs' Complaint.

14 8. Johnson & Johnson denies the allegations contained in Paragraph 8 of
15 Plaintiffs' Complaint.

16 9. Johnson & Johnson admits only that Ethicon, Inc. developed certain pelvic
17 mesh products for uses consistent with the packaging and labeling. Johnson & Johnson
18 does not develop any product. Johnson & Johnson denies the remaining allegations
19 contained in Paragraph 9 of Plaintiffs' Complaint.

20 10. Johnson & Johnson admits only that Ethicon, Inc. designed, manufactured,
21 marketed, promoted, and sold certain pelvic mesh products, including but not limited to
22 Gynecare TVT Obturator System (hereinafter "TVT-O"), for uses consistent with the
23 packaging and labeling, and that they been available for purchase in the State of
24 California. Johnson & Johnson does not design, manufacture, label, package, market,
25 advertise, promote or sell any product. Johnson & Johnson denies the remaining
26 allegations contained in Paragraph 10 of Plaintiffs' Complaint.

27 11. Johnson & Johnson admits only that Ethicon, Inc. designed and
28 manufactured TVT-O for uses consistent with the packaging and labeling. Johnson &

1 Johnson does not design or manufacture any product. Johnson & Johnson lacks sufficient
2 knowledge or information to know whether Plaintiff Julie Cruz was treated with any of
3 Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson &
4 Johnson denies the remaining allegations contained in Paragraph 11 of Plaintiffs'
5 Complaint.

6 12. Johnson & Johnson admits only that Ethicon, Inc. sold TVT-O for uses
7 consistent with the packaging and labeling. Johnson & Johnson does not sell any product.
8 Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff
9 Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson & Johnson
10 denies that allegation. Johnson & Johnson denies the remaining allegations contained in
11 Paragraph 12 of Plaintiffs' Complaint.

12 13. Johnson & Johnson admits only that Ethicon, Inc. sold TVT-O for uses
13 consistent with the packaging and labeling. Johnson & Johnson does not sell any product.
14 Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff
15 Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson & Johnson
16 denies that allegation. Johnson & Johnson denies the remaining allegations contained in
17 Paragraph 13 of Plaintiffs' Complaint.

18 14. Johnson & Johnson admits only that Ethicon, Inc. sold TVT-O for uses
19 consistent with the packaging and labeling, and that it has been available for purchase in
20 the United States, including the State of California. Johnson & Johnson does not design
21 or manufacture any product. Johnson & Johnson denies the remaining allegation
22 contained in Paragraph 14 of Plaintiffs' Complaint.

23 15. Paragraph 15 of Plaintiffs' Complaint makes no allegations against Johnson
24 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
25 required, Johnson & Johnson is without sufficient knowledge or information so as to
26 form a belief as to the truth of the allegations contained in Paragraph 15 of Plaintiffs'
27 Complaint, and, therefore, denies those allegations.
28

1 16. Paragraph 16 of Plaintiffs' Complaint makes no allegations against Johnson
2 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
3 required, Johnson & Johnson is without sufficient knowledge or information so as to
4 form a belief as to the truth of the allegations contained in Paragraph 16 of Plaintiffs'
5 Complaint, and, therefore, denies those allegations.

6 17. Paragraph 17 of Plaintiffs' Complaint makes no allegations against Johnson
7 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
8 required, Johnson & Johnson is without sufficient knowledge or information so as to
9 form a belief as to the truth of the allegations contained in Paragraph 17 of Plaintiffs'
10 Complaint, and, therefore, denies those allegations.

11 18. Paragraph 18 of Plaintiffs' Complaint makes no allegations against Johnson
12 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
13 required, Johnson & Johnson is without sufficient knowledge or information so as to
14 form a belief as to the truth of the allegations contained in Paragraph 18 of Plaintiffs'
15 Complaint, and, therefore, denies those allegations.

16 19. Paragraph 19 of Plaintiffs' Complaint makes no allegations against Johnson
17 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
18 required, Johnson & Johnson is without sufficient knowledge or information so as to
19 form a belief as to the truth of the allegations contained in Paragraph 19 of Plaintiffs'
20 Complaint, and, therefore, denies those allegations.

21 20. Paragraph 20 of Plaintiffs' Complaint makes no allegations against Johnson
22 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
23 required, Johnson & Johnson is without sufficient knowledge or information so as to
24 form a belief as to the truth of the allegations contained in Paragraph 20 of Plaintiffs'
25 Complaint, and, therefore, denies those allegations.

26 21. Paragraph 21 of Plaintiffs' Complaint makes no allegations against Johnson
27 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
28 required, Johnson & Johnson is without sufficient knowledge or information so as to

1 form a belief as to the truth of the allegations contained in Paragraph 21 of Plaintiffs'
2 Complaint, and, therefore, denies those allegations.

3 22. Paragraph 22 of Plaintiffs' Complaint makes no allegations against Johnson
4 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
5 required, Johnson & Johnson is without sufficient knowledge or information so as to
6 form a belief as to the truth of the allegations contained in Paragraph 22 of Plaintiffs'
7 Complaint, and, therefore, denies those allegations.

8 23. Paragraph 23 of Plaintiffs' Complaint states a legal conclusion and requires
9 no response by Johnson & Johnson. To the extent a response is required, Johnson &
10 Johnson is without sufficient knowledge or information so as to form a belief as to the
11 truth of the allegations contained in Paragraph 23 of Plaintiffs' Complaint, and, therefore,
12 denies those factual allegations and legal conclusion.

13 24. Johnson & Johnson admits only that Ethicon, Inc. sold certain pelvic mesh
14 products for uses consistent with the packaging and labeling, and that they have been
15 available for purchase in the State of California. Johnson & Johnson does not sell any
16 product. Johnson & Johnson denies the remaining allegations contained in Paragraph 24
17 of Plaintiffs' Complaint.

18 25. Paragraph 25 of Plaintiffs' Complaint states a legal conclusion and requires
19 no response by Johnson & Johnson. To the extent a response is required, Johnson &
20 Johnson is without sufficient knowledge or information so as to form a belief as to the
21 truth of the allegations contained in Paragraph 25 of Plaintiffs' Complaint, and, therefore,
22 denies those factual allegations and legal conclusion.

23 26. Paragraph 26 of Plaintiffs' Complaint states a legal conclusion and requires
24 no response by Johnson & Johnson. To the extent a response is required, Johnson &
25 Johnson denies the factual allegations and legal conclusion contained in Paragraph 26 of
26 Plaintiffs' Complaint.

27 27. As to the first sentence of Paragraph 27 of Plaintiffs' Complaint, Johnson &
28 Johnson admits only that Ethicon, Inc. sold certain pelvic mesh products for uses

consistent with the packaging and labeling, and that they have been available for purchase in the State of California. Johnson & Johnson does not sell any product. The second sentence of Paragraph 27 of Plaintiffs' Complaint states a legal conclusion and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson is without sufficient knowledge or information so as to form a belief as to those allegations contained in the second sentence of Paragraph 27 of Plaintiffs' Complaint, and, therefore, denies those factual allegations and legal conclusion. Johnson & Johnson denies the remaining allegations contained in Paragraph 27 of Plaintiffs' Complaint.

28. Paragraph 28 of Plaintiffs' Complaint states a legal conclusion and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 28 of Plaintiffs' Complaint, and, therefore, denies those factual allegations and legal conclusion.

RESPONSE TO "FACTUAL BACKGROUND"

A. As Against Johnson & Johnson and Ethicon

29. Johnson & Johnson is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 29 of Plaintiffs' Complaint, and, therefore, denies those allegations.

30. Johnson & Johnson admits only that Ethicon, Inc. manufactured TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not manufacture any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 30 of Plaintiffs' Complaint.

31. Johnson & Johnson admits only that Ethicon, Inc. manufactured TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not manufacture any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 31 of Plaintiffs' Complaint.

32. Johnson & Johnson admits only that Ethicon, Inc. designed, marketed, and sold TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not design, market or sell any product. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 32 of Plaintiffs' Complaint.

33. Johnson & Johnson admits only that Ethicon, Inc. designed, manufactured, marketed, and sold certain pelvic mesh products, including but not limited to TVT-O, for uses consistent with the packaging and labeling. Johnson & Johnson does not design, manufacture, package, label, market, or sell any product. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 33 of Plaintiffs' Complaint.

34. Johnson & Johnson admits only that Ethicon, Inc. designed TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not design any product. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 34 of Plaintiffs' Complaint.

35. Johnson & Johnson admits only that Ethicon, Inc. marketed TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not market any product. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 35 of Plaintiffs' Complaint.

36. Johnson & Johnson admits only that Ethicon, Inc. marketed and promoted TVT-O for uses consistent with the packaging and labeling, and that it has been available

1 for purchase in the United States including the State of California. Johnson & Johnson
2 does not market or promote any product. Johnson & Johnson lacks sufficient knowledge
3 or information to know whether Plaintiff Julie Cruz was treated with any of Ethicon,
4 Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies
5 the remaining allegations contained in Paragraph 36 of Plaintiffs' Complaint.

6 37. Johnson & Johnson admits only that Ethicon, Inc. sold TVT-O for uses
7 consistent with the packaging and labeling. Johnson & Johnson does not sell any product.
8 Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff
9 Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson & Johnson
10 denies that allegation. Johnson & Johnson denies the remaining allegations contained in
11 Paragraph 37 of Plaintiffs' Complaint.

12 38. Johnson & Johnson admits only that Ethicon, Inc. sold TVT-O for uses
13 consistent with the packaging and labeling. Johnson & Johnson does not sell any product.
14 Johnson & Johnson denies the remaining allegations contained in Paragraph 38 of
15 Plaintiffs' Complaint.

16 39. Johnson & Johnson admits only that Ethicon, Inc. sold TVT-O for uses
17 consistent with the packaging and labeling. Johnson & Johnson does not sell any product.
18 Johnson & Johnson denies the remaining allegations contained in Paragraph 39 of
19 Plaintiffs' Complaint.

20 40. Johnson & Johnson admits only that Ethicon, Inc. sold TVT-O for uses
21 consistent with the packaging and labeling, and that it has been available for purchase in
22 the United States including the State of California. Johnson & Johnson does not sell any
23 product. Johnson & Johnson denies the remaining allegations contained in Paragraph 40
24 of Plaintiffs' Complaint.

25 41. Paragraph 41 of Plaintiffs' Complaint makes no allegation against Johnson
26 & Johnson and requires no response by Johnson & Johnson.

27 42. Paragraph 42 of Plaintiffs' Complaint makes no allegation against Johnson
28 & Johnson and requires no response by Johnson & Johnson.

43. Paragraph 43 of Plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson admits only that Ethicon, Inc. marketed TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not market any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 43 of Plaintiffs' Complaint as phrased.

44. Paragraph 44 of Plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson denies the allegations contained in Paragraph 44 of Plaintiffs' Complaint.

45. Johnson & Johnson admits that Ethicon, Inc. manufactured TVT-O for uses consistent with the packaging and labeling, and that it has been classified by the FDA as a regulatory Class II device. Johnson & Johnson does not manufacture any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 45 of Plaintiffs' Complaint.

46. Johnson & Johnson admits that the FDA cleared TVT-O under the 510(k) Premarket Notification. Johnson & Johnson denies the remaining allegations contained in Paragraph 46 of Plaintiffs' Complaint.

47. Johnson & Johnson denies the allegations contained in Paragraph 47 of Plaintiffs' Complaint.

48. Johnson & Johnson lacks sufficient knowledge to know whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 48 of Plaintiffs' Complaint.

B. As Against Coloplast

49. Paragraphs 49 through 64 of Plaintiffs' Complaint make no allegations against Johnson & Johnson and require not response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson is without sufficient knowledge or

1 information so as to form a belief as to the truth of the allegations contained in these
2 paragraphs, and, therefore, denies those allegations.

3 **C. Facts Common to All Defendants**

4 65. Paragraph 65 of Plaintiffs' Complaint makes no allegations against Johnson
5 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
6 required, Johnson & Johnson admits that Ethicon, Inc. marketed TVT-O for uses
7 consistent with the packaging and labeling, and that it is safe and effective for uses
8 consistent with the packaging and labeling. Johnson & Johnson does not market any
9 product. Johnson & Johnson is without sufficient knowledge or information so as to form
10 a belief as to the truth of the remaining allegations contained in Paragraph 65 of
11 Plaintiffs' Complaint, and, therefore, Johnson & Johnson denies those allegations.

12 66. Paragraph 66 of Plaintiffs' Complaint makes no allegations against Johnson
13 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
14 required, Johnson & Johnson admits only that the July 13, 2011 FDA Safety
15 Communication speaks for itself. Johnson & Johnson denies any remaining allegations
16 contained in Paragraph 66 of Plaintiffs' Complaint.

17 67. Paragraph 67 of Plaintiffs' Complaint makes no allegations against Johnson
18 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
19 required, Johnson & Johnson admits only that the July 13, 2011 FDA Safety
20 Communication speaks for itself. Johnson & Johnson denies any remaining allegations
21 contained in Paragraph 67 of Plaintiffs' Complaint.

22 68. Paragraph 68 of Plaintiffs' Complaint makes no allegations against Johnson
23 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
24 required, Johnson & Johnson admits only that the July 13, 2011 FDA Safety
25 Communication speaks for itself. Johnson & Johnson denies the remaining allegations
26 contained in Paragraph 68 of Plaintiffs' Complaint.

27 69. Paragraph 69 of Plaintiffs' Complaint makes no allegations against Johnson
28 & Johnson and requires no response by Johnson & Johnson. To the extent a response is

1 required, Johnson & Johnson admits only that the July 13, 2011 FDA Safety
2 Communication speaks for itself. Johnson & Johnson denies any remaining allegations
3 contained in Paragraph 69 of Plaintiffs' Complaint.

4 70. Paragraph 70 of Plaintiffs' Complaint makes no allegations against Johnson
5 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
6 required, Johnson & Johnson admits only that the referenced publication speaks for itself.
7 Johnson & Johnson denies any remaining allegations contained in Paragraph 70 of
8 Plaintiffs' Complaint.

9 71. Paragraph 71 of Plaintiffs' Complaint makes no allegations against Johnson
10 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
11 required, Johnson & Johnson admits only that the referenced publication speaks for itself.
12 Johnson & Johnson denies any remaining allegations contained in Paragraph 71 of
13 Plaintiffs' Complaint.

14 72. Paragraph 72 of Plaintiffs' Complaint makes no allegations against Johnson
15 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
16 required, Johnson & Johnson admits only that the referenced publication speaks for itself.
17 Johnson & Johnson denies any remaining allegations contained in Paragraph 72 of
18 Plaintiffs' Complaint.

19 73. Paragraph 73 of Plaintiffs' Complaint makes no allegations against Johnson
20 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
21 required, Johnson & Johnson admits only that the referenced publication speaks for itself.
22 Johnson & Johnson denies any remaining allegations contained in Paragraph 73 of
23 Plaintiffs' Complaint.

24 74. Paragraph 74 of Plaintiffs' Complaint makes no allegations against Johnson
25 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
26 required, Johnson & Johnson admits only that the referenced publication speaks for itself.
27 Johnson & Johnson denies any remaining allegations contained in Paragraph 74 of
28 Plaintiffs' Complaint.

75. Johnson & Johnson denies the allegations contained in Paragraph 75 of Plaintiffs' Complaint.

76. Johnson & Johnson denies the allegations contained in Paragraph 76 of Plaintiffs' Complaint.

77. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and, Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 77 of Plaintiffs' Complaint.

78. Johnson & Johnson denies the allegations contained in Paragraph 78 of Plaintiffs' Complaint.

79. The first two sentences of Paragraph 79 of Plaintiffs' Complaint make no allegations against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson admits that the FDA's website speaks for itself. Johnson & Johnson denies the remaining allegations contained in Paragraph 79 of Plaintiffs' Complaint.

80. Johnson & Johnson denies the allegations contained in Paragraph 80 of Plaintiffs' Complaint.

81. Johnson & Johnson denies the allegation contained in Paragraph 81 of Plaintiffs' Complaint.

82. Johnson & Johnson admits only that Ethicon, Inc. marketed TVT-O for uses consistent with the packaging and labeling, and that it is safe and effective for uses consistent with the packaging and labeling. Johnson & Johnson does not market any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 82 of Plaintiffs' Complaint.

83. Johnson & Johnson admits that Ethicon, Inc. promoted, marketed, sold and distributed TVT-O for uses consistent with the packaging and labeling, and that it is safe and effective for uses consistent with the packaging and labeling. Johnson & Johnson does not advertise, promote, market, sell or distribute any product. Johnson & Johnson

1 lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was
2 treated with any of Ethicon, Inc.'s products, and Johnson & Johnson denies that
3 allegation. Johnson & Johnson denies the remaining allegations contained Paragraph 83
4 Plaintiffs' Complaint.

5 84. Johnson & Johnson lacks sufficient knowledge or information to know
6 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
7 & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations
8 contained in Paragraph 84 of Plaintiffs' Complaint.

9 85. Johnson & Johnson denies the allegations contained in Paragraph 85 of
10 Plaintiffs' Complaint, including subparts (a.) – (l.)

11 86. Johnson & Johnson denies the allegations contained in Paragraph 86 of
12 Plaintiffs' Complaint, including subparts (m.) – (dd.).

13 87. Johnson & Johnson denies the allegations contained in Paragraph 87 of
14 Plaintiffs' Complaint.

15 88. Johnson & Johnson denies the allegations contained in Paragraph 88 of
16 Plaintiffs' Complaint.

17 89. Johnson & Johnson denies the allegations contained Paragraph 89 of
18 Plaintiffs' Complaint.

19 90. Johnson & Johnson denies the allegations contained in Paragraph 90 of
20 Plaintiffs' Complaint.

21 91. Johnson & Johnson admits only that Ethicon, Inc. sold TVT-O for uses
22 consistent with the packaging and labeling. Johnson & Johnson does not sell any product.
23 Johnson & Johnson denies the remaining allegations contained in Paragraph 91 of
24 Plaintiffs' Complaint.

25 92. Johnson & Johnson denies the allegations contained in Paragraph 92 of
26 Plaintiffs' Complaint.

27 93. Johnson & Johnson admits only that Ethicon, Inc. sold TVT-O for uses
28 consistent with the packaging and labeling. Johnson & Johnson does not sell any product.

1 Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff
2 Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson & Johnson
3 denies that allegation. Johnson & Johnson denies the remaining allegations contained in
4 Paragraph 93 of Plaintiffs' Complaint.

5 94. Johnson & Johnson denies the allegations contained in Paragraph 94 of
6 Plaintiffs' Complaint.

7 95. Johnson & Johnson denies the allegations contained in Paragraph 95 of
8 Plaintiffs' Complaint.

9 96. Johnson & Johnson lacks sufficient knowledge or information to know
10 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
11 & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations
12 contained in Paragraph 96 of Plaintiffs' Complaint.

13 97. Johnson & Johnson denies the allegations contained in Paragraph 97 of
14 Plaintiffs' Complaint.

15 98. Johnson & Johnson admits that Ethicon, Inc. promoted TVT-O for uses
16 consistent with the packaging and labeling, and that it is safe and effective for uses
17 consistent with the packaging and labeling. Johnson & Johnson does not promote any
18 product. Johnson & Johnson denies the remaining allegations contained in Paragraph 98
19 of Plaintiffs' Complaint.

20 99. Johnson & Johnson denies the allegations contained in Paragraph 99 of
21 Plaintiffs' Complaint.

22 100. Johnson & Johnson denies the allegations contained in Paragraph 100
23 Plaintiffs' Complaint.

24 101. Johnson & Johnson denies the allegations contained in Paragraph 101
25 Plaintiffs' Complaint.

26 102. Johnson & Johnson lacks sufficient knowledge or information to know
27 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
28

1 & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations
2 contained in Paragraph 102 Plaintiffs' Complaint.

3 **RESPONSE TO "CAUSES OF ACTION:**

4 **COUNT I: NEGLIGENCE"**

5 103. Johnson & Johnson incorporates by reference its responses to each and every
6 allegation contained in Plaintiffs' Complaint.

7 104. Johnson & Johnson admits that Ethicon, Inc. has certain duties imposed on it
8 by law, but denies that Ethicon, Inc. breached any duty. Johnson & Johnson admits that
9 Ethicon, Inc. designed, manufactured, marketed, and sold TVT-O for uses consistent with
10 the packaging and labeling. Johnson & Johnson does not design, manufacture, market,
11 package, label, or sell any product. Johnson & Johnson denies the remaining allegations
12 contained in Paragraph 104 of Plaintiffs' Complaint.

13 105. Johnson & Johnson denies the allegations contained in Paragraph 105 of
14 Plaintiffs' Complaint, including the bulleted subparts.

15 106. Paragraph 106 of Plaintiffs' Complaint makes no allegations against Johnson
16 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
17 required, Johnson & Johnson is without sufficient knowledge or information so as to
18 form a belief as to the truth of the allegations contained in Paragraph 106 of Plaintiffs'
19 Complaint, and, therefore, Johnson & Johnson denies those allegations.

20 107. Paragraph 107 of Plaintiffs' Complaint makes no allegations against Johnson
21 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
22 required, Johnson & Johnson is without sufficient knowledge or information so as to
23 form a belief as to the truth of the allegations contained in Paragraph 107 of Plaintiffs'
24 Complaint, and, therefore, Johnson & Johnson denies those allegations.

25 108. Johnson & Johnson denies the allegations contained in Paragraph 108 of
26 Plaintiffs' Complaint, including the bulleted subparts.

**RESPONSE TO “COUNT II: STRICT LIABILITY -
MANUFACTURING DEFECT”**

109. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Plaintiffs’ Complaint.

110. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.’s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 110 of Plaintiffs’ Complaint.

111. Paragraph 111 of Plaintiffs’ Complaint makes no allegations against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 111 of Plaintiffs’ Complaint, and, therefore, Johnson & Johnson denies those allegations.

112. Johnson & Johnson denies the allegations contained in Paragraph 112 of Plaintiffs’ Complaint.

113. Johnson & Johnson denies the allegations contained in Paragraph 113 of Plaintiffs’ Complaint.

**RESPONSE TO “COUNT III: STRICT LIABILITY –
FAILURE TO WARN”**

114. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Plaintiffs’ Complaint.

115. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.’s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 115 of Plaintiffs’ Complaint, including the bulleted subparts.

116. Paragraph 116 of Plaintiffs’ Complaint makes no allegations against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson is without sufficient knowledge or information so as to

1 form a belief as to the truth of the allegations contained in Paragraph 116 of Plaintiffs'
2 Complaint, and, therefore, Johnson & Johnson denies those allegations.

3 117. Johnson & Johnson denies the allegations contained in Paragraph 117 of
4 Plaintiffs' Complaint.

5 118. Johnson & Johnson denies the allegations contained in Paragraph 118 of
6 Plaintiffs' Complaint.

7 **RESPONSE TO "COUNT IV:**
8 **FRAUDULENT CONCEALMENT"**

9 119. Johnson & Johnson incorporates by reference its responses to each and every
10 allegation contained in Plaintiffs' Complaint.

11 120. Johnson & Johnson admits that TVT-O is safe and effective for uses
12 consistent with the packaging and labeling. Johnson & Johnson denies the remaining
13 allegations contained in Paragraph 120 of Plaintiffs' Complaint.

14 121. Paragraph 121 of Plaintiffs' Complaint makes no allegations against Johnson
15 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
16 required, Johnson & Johnson is without sufficient knowledge or information so as to
17 form a belief as to the truth of the allegations contained in Paragraph 121 of Plaintiffs'
18 Complaint, and, therefore, Johnson & Johnson denies those allegations.

19 122. Johnson & Johnson denies the allegations contained in Paragraph 122 of
20 Plaintiffs' Complaint.

21 123. Johnson & Johnson admits it has certain duties imposed on it by law, but
22 denies that it breached any duty. Johnson & Johnson denies the remaining allegations
23 contained in Paragraph 123 of Plaintiffs' Complaint.

24 124. Johnson & Johnson lacks sufficient knowledge or information to know
25 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
26 & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations
27 contained in Paragraph 124 of Plaintiffs' Complaint.
28

1 125. Johnson & Johnson denies the allegations contained in Paragraph 125 of
2 Plaintiffs' Complaint.

3 126. Johnson & Johnson denies the allegations contained in Paragraph 126 of
4 Plaintiffs' Complaint.

5 127. Paragraph 127 of Plaintiffs' Complaint makes no allegations against Johnson
6 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
7 required, Johnson & Johnson is without sufficient knowledge or information so as to
8 form a belief as to the truth of the allegations contained in Paragraph 127 of Plaintiffs'
9 Complaint, and, therefore, Johnson & Johnson denies those allegations.

10 128. Paragraph 128 of Plaintiffs' Complaint makes no allegations against Johnson
11 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
12 required, Johnson & Johnson is without sufficient knowledge or information so as to
13 form a belief as to the truth of the allegations contained in Paragraph 128 of Plaintiffs'
14 Complaint, and, therefore, Johnson & Johnson denies those allegations.

15 129. Paragraph 129 of Plaintiffs' Complaint makes no allegations against Johnson
16 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
17 required, Johnson & Johnson is without sufficient knowledge or information so as to
18 form a belief as to the truth of the allegations contained in Paragraph 129 of Plaintiffs'
19 Complaint, and, therefore, Johnson & Johnson denies those allegations.

20 130. Paragraph 130 of Plaintiffs' Complaint makes no allegations against Johnson
21 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
22 required, Johnson & Johnson is without sufficient knowledge or information so as to
23 form a belief as to the truth of the allegations contained in Paragraph 130 of Plaintiffs'
24 Complaint, and, therefore, Johnson & Johnson denies those allegations.

25 131. Johnson & Johnson denies the allegations contained in Paragraph 131 of
26 Plaintiffs' Complaint.

27 132. Johnson & Johnson denies the allegations contained in Paragraph 132 of
28 Plaintiffs' Complaint.

133. Johnson & Johnson denies the allegations contained in Paragraph 133 of Plaintiffs' Complaint.

134. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Plaintiffs' Complaint.

135. Johnson & Johnson denies the allegations contained in Paragraph 135 of Plaintiffs' Complaint.

136. Johnson & Johnson denies the allegations contained in Paragraph 136 of Plaintiffs' Complaint.

137. Paragraph 137 of Plaintiffs' Complaint makes no allegations against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 137 of Plaintiffs' Complaint, and, therefore, denies those allegations.

138. Johnson & Johnson denies the allegations contained in Paragraph 138 of Plaintiffs' Complaint.

139. Johnson & Johnson denies the allegations contained in Paragraph 139 of Plaintiffs' Complaint.

140. Paragraph 140 of Plaintiffs' Complaint makes no allegations against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 140 of Plaintiffs' Complaint, and, therefore, denies those allegations.

141. Paragraph 141 of Plaintiffs' Complaint makes no allegations against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson is without sufficient knowledge or information so as to

1 form a belief as to the truth of the allegations contained in Paragraph 141 of Plaintiffs'
2 Complaint, and, therefore, denies those allegations.

3 142. Paragraph 142 of Plaintiffs' Complaint makes no allegations against Johnson
4 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
5 required, Johnson & Johnson is without sufficient knowledge or information so as to
6 form a belief as to the truth of the allegations contained in Paragraph 142 of Plaintiffs'
7 Complaint, and, therefore, denies those allegations.

8 143. Paragraph 143 of Plaintiffs' Complaint makes no allegations against Johnson
9 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
10 required, Johnson & Johnson is without sufficient knowledge or information so as to
11 form a belief as to the truth of the allegations contained in Paragraph 143 of Plaintiffs'
12 Complaint, and, therefore, denies those allegations.

13 144. Paragraph 144 of Plaintiffs' Complaint makes no allegations against Johnson
14 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
15 required, Johnson & Johnson is without sufficient knowledge or information so as to
16 form a belief as to the truth of the allegations contained in Paragraph 144 of Plaintiffs'
17 Complaint, and, therefore, denies those allegations.

18 **RESPONSE TO "VI:**

19 **BREACH OF IMPLIED WARRANTY"**

20 145. Johnson & Johnson incorporates by reference its responses to each and every
21 allegation contained in Plaintiffs' Complaint.

22 146. Johnson & Johnson admits that TVT-O is safe and effective for uses
23 consistent with the packaging and labeling. Johnson & Johnson denies the remaining
24 allegations contained in Paragraph 146 of Plaintiffs' Complaint.

25 147. Johnson & Johnson lacks sufficient knowledge or information to know
26 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
27 & Johnson denies that allegation. Johnson & Johnson admits only that Ethicon, Inc. sold
28 TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not

1 sell any product. Johnson & Johnson denies the remaining allegations contained in
2 Paragraph 147 of Plaintiffs' Complaint.

3 148. Johnson & Johnson lacks sufficient knowledge or information to know
4 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
5 & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations
6 contained in Paragraph 148 of Plaintiffs' Complaint.

7 149. Johnson & Johnson denies the allegations contained in Paragraph 149 of
8 Plaintiffs' Complaint.

9 150. Johnson & Johnson lacks sufficient knowledge or information to know
10 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
11 & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations
12 contained in Paragraph 150 of Plaintiffs' Complaint.

13 151. Paragraph 151 of Plaintiffs' Complaint makes no allegations against Johnson
14 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
15 required, Johnson & Johnson is without sufficient knowledge or information so as to
16 form a belief as to the truth of the allegations contained in Paragraph 151 of Plaintiffs'
17 Complaint, and, therefore, denies those allegations.

18 152. Paragraph 152 of Plaintiffs' Complaint makes no allegations against Johnson
19 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
20 required, Johnson & Johnson is without sufficient knowledge or information so as to
21 form a belief as to the truth of the allegations contained in Paragraph 152 of Plaintiffs'
22 Complaint, and, therefore, denies those allegations.

23 153. Paragraph 153 of Plaintiffs' Complaint makes no allegations against Johnson
24 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
25 required, Johnson & Johnson is without sufficient knowledge or information so as to
26 form a belief as to the truth of the allegations contained in Paragraph 153 of Plaintiffs'
27 Complaint, and, therefore, denies those allegations.
28

1 154. Paragraph 154 of Plaintiffs' Complaint makes no allegations against Johnson
2 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
3 required, Johnson & Johnson is without sufficient knowledge or information so as to
4 form a belief as to the truth of the allegations contained in Paragraph 154 of Plaintiffs'
5 Complaint, and, therefore, denies those allegations.

6 155. Paragraph 155 of Plaintiffs' Complaint makes no allegations against Johnson
7 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
8 required, Johnson & Johnson is without sufficient knowledge or information so as to
9 form a belief as to the truth of the allegations contained in Paragraph 155 of Plaintiffs'
10 Complaint, and, therefore, denies those allegations.

11 156. Johnson & Johnson denies the allegations contained in Paragraph 156 of
12 Plaintiffs' Complaint.

13 157. Johnson & Johnson denies the allegations contained in Paragraph 157 of
14 Plaintiffs' Complaint.

15 158. Johnson & Johnson denies the allegations contained in Paragraph 158 of
16 Plaintiffs' Complaint.

17 **RESPONSE TO "COUNT VII:**
18 **NEGLIGENT MISREPRESENTATION"**

19 159. Johnson & Johnson incorporates by reference its responses to each and every
20 allegation contained in Plaintiffs' Complaint.

21 160. Johnson & Johnson admits that TVT-O is safe and effective for uses
22 consistent with the packaging and labeling. Johnson & Johnson denies the remaining
23 allegations contained in Paragraph 160 of Plaintiffs' Complaint.

24 161. Johnson & Johnson denies the allegations contained in Paragraph 161 of
25 Plaintiffs' Complaint.

26 162. Johnson & Johnson admits only that Ethicon, Inc. promoted TVT-O for uses
27 consistent with the packaging and labeling, and that it is safe and effective for uses
28 consistent with the packaging and labeling. Johnson & Johnson does not promote any

1 product. Johnson & Johnson denies the remaining allegations contained in Paragraph 162
2 of Plaintiffs' Complaint.

3 163. Johnson & Johnson denies the allegations contained in Paragraph 163 of
4 Plaintiffs' Complaint.

5 164. Johnson & Johnson lacks sufficient knowledge or information to know
6 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
7 & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations
8 contained in Paragraph 164 of Plaintiffs' Complaint.

9 165. Paragraph 165 of Plaintiffs' Complaint makes no allegations against Johnson
10 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
11 required, Johnson & Johnson is without sufficient knowledge or information so as to
12 form a belief as to the truth of the allegations contained in Paragraph 165 of Plaintiffs'
13 Complaint, and, therefore, denies those allegations.

14 166. Paragraph 166 of Plaintiffs' Complaint makes no allegations against Johnson
15 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
16 required, Johnson & Johnson is without sufficient knowledge or information so as to
17 form a belief as to the truth of the allegations contained in Paragraph 166 of Plaintiffs'
18 Complaint, and, therefore, denies those allegations.

19 167. Paragraph 167 of Plaintiffs' Complaint makes no allegations against Johnson
20 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
21 required, Johnson & Johnson is without sufficient knowledge or information so as to
22 form a belief as to the truth of the allegations contained in Paragraph 167 of Plaintiffs'
23 Complaint, and, therefore, denies those allegations.

24 168. Paragraph 168 of Plaintiffs' Complaint makes no allegations against Johnson
25 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
26 required, Johnson & Johnson is without sufficient knowledge or information so as to
27 form a belief as to the truth of the allegations contained in Paragraph 168 of Plaintiffs'
28 Complaint, and, therefore, denies those allegations.

1 169. Paragraph 169 of Plaintiffs' Complaint makes no allegations against Johnson
2 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
3 required, Johnson & Johnson is without sufficient knowledge or information so as to
4 form a belief as to the truth of the allegations contained in Paragraph 169 of Plaintiffs'
5 Complaint, and, therefore, denies those allegations.

6 170. Johnson & Johnson denies the allegations contained in Paragraph 170 of
7 Plaintiffs' Complaint.

8 **RESPONSE TO "COUNT VIII:**
9 **NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS"**

10 171. Johnson & Johnson incorporates by reference its responses to each and every
11 allegation contained in Plaintiffs' Complaint.

12 172. Johnson & Johnson denies the allegations contained in Paragraph 172 of
13 Plaintiffs' Complaint.

14 173. Johnson & Johnson lacks sufficient knowledge or information to know
15 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
16 & Johnson denies that allegation. Johnson & Johnson admits only that Ethicon, Inc. sold
17 and distributed TVT-O for uses consistent with the packaging and labeling. Johnson &
18 Johnson does not sell or distribute any product. Johnson & Johnson denies the remaining
19 allegations contained in Paragraph 173 of Plaintiffs' Complaint.

20 174. Paragraph 174 of Plaintiffs' Complaint makes no allegations against Johnson
21 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
22 required, Johnson & Johnson is without sufficient knowledge or information so as to
23 form a belief as to the truth of the allegations contained in Paragraph 174 of Plaintiffs'
24 Complaint, and, therefore, denies those allegations.

25 175. Paragraph 175 of Plaintiffs' Complaint makes no allegations against Johnson
26 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
27 required, Johnson & Johnson is without sufficient knowledge or information so as to
28

1 form a belief as to the truth of the allegations contained in Paragraph 175 of Plaintiffs'
2 Complaint, and, therefore, denies those allegations.

3 176. Johnson & Johnson denies the allegations contained in Paragraph 176 of
4 Plaintiffs' Complaint.

5 **RESPONSE TO "COUNT IX:**
6 **BREACH OF EXPRESS WARRANTY"**

7 177. Johnson & Johnson incorporates by reference its responses to each and every
8 allegation contained in Plaintiffs' Complaint.

9 178. As to the first sentence of Paragraph 178 of Plaintiffs' Complaint, Johnson
10 & Johnson admits that TVT-O is safe and effective for uses consistent with the packaging
11 and labeling. The second sentence of Paragraph 178 of Plaintiffs' Complaint makes no
12 allegations against Johnson & Johnson and requires no response by Johnson & Johnson.
13 To the extent a response is required, Johnson & Johnson is without sufficient knowledge
14 or information so as to form a belief as to the truth of the allegations contained in the
15 second sentence of Paragraph 178 of Plaintiffs' Complaint. Johnson & Johnson denies
16 the remaining allegations contained in Paragraph 178 of Plaintiffs' Complaint.

17 179. Johnson & Johnson lacks sufficient knowledge or information to know
18 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
19 & Johnson denies that allegation. Johnson & Johnson admits only that TVT-O is safe and
20 effective for uses consistent with the packaging and labeling. Johnson & Johnson denies
21 the remaining allegations contained in Paragraph 179 of Plaintiffs' Complaint as they
22 relate to Johnson & Johnson.

23 180. Johnson & Johnson admits that TVT-O is safe and effective for uses
24 consistent with the packaging and labeling. Johnson & Johnson denies the remaining
25 allegations contained in Paragraph 180 of Plaintiffs' Complaint.

26 181. Johnson & Johnson lacks sufficient knowledge or information to know
27 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
28

1 & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations
2 contained in Paragraph 181 of Plaintiffs' Complaint.

3 182. As to the first sentence of Paragraph 182 of Plaintiffs' Complaint, Johnson
4 & Johnson admits that TVT-O is safe and effective for uses consistent with the packaging
5 and labeling. The second sentence of Paragraph 182 of Plaintiffs' Complaint makes no
6 allegations against Johnson & Johnson and requires no response by Johnson & Johnson.
7 To the extent a response is required, Johnson & Johnson is without sufficient knowledge
8 or information so as to form a belief as to the truth of the allegations contained in the
9 second sentence of Paragraph 182 of Plaintiffs' Complaint, and, therefore, denies those
10 allegations. Johnson & Johnson denies the remaining allegations contained in Paragraph
11 182 of Plaintiffs' Complaint.

12 183. Johnson & Johnson denies the allegations contained in Paragraph 183 of
13 Plaintiffs' Complaint.

14 184. Paragraph 184 of Plaintiffs' Complaint makes no allegations against Johnson
15 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
16 required, Johnson & Johnson is without sufficient knowledge or information so as to
17 form a belief as to the truth of the allegations contained in Paragraph 184 of Plaintiffs'
18 Complaint, and, therefore, denies those allegations.

19 185. Johnson & Johnson lacks sufficient knowledge or information to know
20 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
21 & Johnson denies that allegation. Johnson & Johnson admits only that TVT-O is safe and
22 effective for uses consistent with the packaging and labeling. Johnson & Johnson denies
23 the remaining allegations contained in Paragraph 185 of Plaintiffs' Complaint as they
24 relate to Johnson & Johnson.

25 186. Johnson & Johnson lacks sufficient knowledge or information to know
26 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
27 & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations
28 contained in Paragraph 186 of Plaintiffs' Complaint.

1 187. Johnson & Johnson denies the allegations contained in Paragraph 187 of
2 Plaintiffs' Complaint.

3 188. Johnson & Johnson denies the allegations contained in Paragraph 188 of
4 Plaintiffs' Complaint.

5 **RESPONSE TO "COUNT X:**

6 **GROSS NEGLIGENCE**

7 189. Johnson & Johnson incorporates by reference its responses to each and every
8 allegation contained in Plaintiffs' Complaint.

9 190. Johnson & Johnson denies the allegations contained in Paragraph 190 of
10 Plaintiffs' Complaint. Johnson & Johnson denies that Plaintiffs are entitled to any
11 recovery or any form of relief whatsoever from Johnson & Johnson.

12 191. Johnson & Johnson denies the allegations contained in Paragraph 191 of
13 Plaintiffs' Complaint.

14 192. Johnson & Johnson denies the allegations contained in Paragraph 192 of
15 Plaintiffs' Complaint. Johnson & Johnson denies that Plaintiffs are entitled to any
16 recovery or any form of relief whatsoever from Johnson & Johnson.

17 193. Johnson & Johnson denies the allegations contained in Paragraph 193 of
18 Plaintiffs' Complaint. Johnson & Johnson denies that Plaintiffs are entitled to any
19 recovery or any form of relief whatsoever from Johnson & Johnson.

20 **RESPONSE TO "COUNT XI:**

21 **UNJUST ENRICHMENT"**

22 194. Johnson & Johnson incorporates by reference its responses to each and every
23 allegation contained in Plaintiffs' Complaint.

24 195. Johnson & Johnson lacks sufficient knowledge or information to know
25 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
26 & Johnson denies that allegation. Johnson & Johnson admits only that Ethicon, Inc. sold
27 TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not
28

1 sell any product. Johnson & Johnson denies the remaining allegations contained in
2 Paragraph 195 of Plaintiffs' Complaint.

3 196. Johnson & Johnson lacks sufficient knowledge or information to know
4 whether Plaintiff Julie Cruz was treated with any of Ethicon, Inc.'s products, and Johnson
5 & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations
6 contained in Paragraph 196 of Plaintiffs' Complaint.

7 197. Paragraph 197 of Plaintiffs' Complaint makes no allegations against Johnson
8 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
9 required, Johnson & Johnson is without sufficient knowledge or information so as to
10 form a belief as to the truth of the allegations contained in Paragraph 197 of Plaintiffs'
11 Complaint, and, therefore, denies those allegations.

12 198. Paragraph 198 of Plaintiffs' Complaint makes no allegations against Johnson
13 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
14 required, Johnson & Johnson is without sufficient knowledge or information so as to
15 form a belief as to the truth of the allegations contained in Paragraph 198 of Plaintiffs'
16 Complaint, and, therefore, denies those allegations.

17 199. Johnson & Johnson denies the allegations contained in Paragraph 199 of
18 Plaintiffs' Complaint.

19 200. Johnson & Johnson denies the allegations contained in Paragraph 200 of
20 Plaintiffs' Complaint.

21 **RESPONSE TO "COUNT XII:**
22 **LOSS OF CONSORTIUM"**

23 201. Johnson & Johnson incorporates by reference its responses to each and every
24 allegation contained in Plaintiffs' Complaint.

25 202. Johnson & Johnson denies the allegations contained in Paragraph 202 of
26 Plaintiffs' Complaint.

RESPONSE TO “COUNT XIII:
PUNITIVE DAMAGES”

203. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Plaintiffs’ Complaint.

204. Johnson & Johnson denies the allegations contained in Paragraph 204 of Plaintiffs’ Complaint.

205. Johnson & Johnson admits that Ethicon, Inc. sold and tested TVT-O for uses consistent with the packaging and labeling, and that it has been available for purchase in the United States including the State of California. Johnson & Johnson admits further that TVT-O is safe and effective for uses consistent with the packaging and labeling. Johnson & Johnson does not sell or test any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 205 of Plaintiffs’ Complaint.

206. Johnson & Johnson admits that Ethicon, Inc. sold TVT-O for uses consistent with the packaging and labeling, and that it has been available for purchase in the United States including the State of California. Johnson & Johnson does not sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 206 of Plaintiffs’ Complaint.

207. Johnson & Johnson admits that Ethicon, Inc. marketed and sold TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not market or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 207 of Plaintiffs’ Complaint.

208. Paragraph 208 of Plaintiffs’ Complaint makes no allegations against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 208 of Plaintiffs’ Complaint, and, therefore, denies those allegations.

209. Paragraph 209 of Plaintiffs’ Complaint makes no allegations against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is

1 required, Johnson & Johnson is without sufficient knowledge or information so as to
 2 form a belief as to the truth of the allegations contained in Paragraph 209 of Plaintiffs'
 3 Complaint, and, therefore, denies those allegations.

4 210. Paragraph 210 of Plaintiffs' Complaint makes no allegations against Johnson
 5 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
 6 required, Johnson & Johnson is without sufficient knowledge or information so as to
 7 form a belief as to the truth of the allegations contained in Paragraph 210 of Plaintiffs'
 8 Complaint, and, therefore, denies those allegations.

9 211. Paragraph 211 of Plaintiffs' Complaint makes no allegations against Johnson
 10 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
 11 required, Johnson & Johnson is without sufficient knowledge or information so as to
 12 form a belief as to the truth of the allegations contained in Paragraph 211 of Plaintiffs'
 13 Complaint, and, therefore, denies those allegations.

14 212. Johnson & Johnson denies the allegations contained in Paragraph 212 of
 15 Plaintiffs' Complaint.

16 213. Johnson & Johnson denies the allegations contained in Paragraph 213 of
 17 Plaintiffs' Complaint. Johnson & Johnson denies that Plaintiffs are entitled to any
 18 recovery or any form of relief whatsoever from Johnson & Johnson.

19 **RESPONSE TO "COUNT XIV:**

20 **DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT"**

21 214. Johnson & Johnson incorporates by reference its responses to each and every
 22 allegation contained in Plaintiffs' Complaint.

23 215. Paragraph 215 of Plaintiffs' Complaint makes no allegations against Johnson
 24 & Johnson and requires no response by Johnson & Johnson. To the extent a response is
 25 required, Johnson & Johnson denies the allegations contained in Paragraph 215 of
 26 Plaintiffs' Complaint.

27 216. Johnson & Johnson denies the allegations contained in Paragraph 216 of
 28 Plaintiffs' Complaint.

217. Paragraph 217 of Plaintiffs' Complaint states a legal conclusion and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in paragraph 217 of Plaintiffs' Complaint, and, therefore, denies those allegations.

218. Paragraph 218 of Plaintiffs' Complaint states a legal conclusion and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson denies the allegations contained in Paragraph 218 of Plaintiffs' Complaint.

RESPONSE TO "PRAYER FOR RELIEF"

In response to the unnumbered WHEREFORE paragraph under the "Prayer for Relief" subsection of Plaintiffs' Complaint, Ethicon denies that Plaintiffs are entitled to any recovery or any form of relief whatsoever from Ethicon. Ethicon denies any remaining allegations, including subparts (i.) – (v.).

RESPONSE TO "JURY DEMAND"

Johnson & Johnson hereby demands a trial by jury.

Johnson & Johnson denies any and all allegations contained in Plaintiffs' Complaint not specifically admitted hereinabove.

DEFENSES

FIRST DEFENSE

Plaintiffs' claims against Johnson & Johnson are barred because Johnson & Johnson does not design, develop, manufacture, market, promote or sell any product allegedly at issue in this action.

SECOND DEFENSE

Johnson & Johnson has never had possession or control over the product at issue in this action, and therefore the Complaint as to each cause of action fails to state a claim against Johnson & Johnson.

THIRD DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted.

FOURTH DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted due to lack of adequate product identification.

FIFTH DEFENSE

Plaintiffs' claims are barred for lack of subject matter jurisdiction.

SIXTH DEFENSE

Plaintiffs' claims are barred for lack of personal jurisdiction.

SEVENTH DEFENSE

The Complaint must be dismissed because Plaintiffs provided insufficient process.

EIGHTH DEFENSE

The Complaint must be dismissed because Plaintiffs provided insufficient service of process.

NINTH DEFENSE

Plaintiffs may be barred from bringing some of the claims alleged in the Complaint because Plaintiffs may lack standing and/or capacity to bring such claims.

TENTH DEFENSE

Plaintiffs' claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction or the laws of the United States.

ELEVENTH DEFENSE

Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

TWELFTH DEFENSE

Venue in this Court is improper, and this matter should be dismissed on forum non conveniens grounds.

THIRTEENTH DEFENSE

Plaintiffs' alleged causes of action have been improperly joined under the applicable Rules of Civil Procedure and the laws of the applicable state.

FOURTEENTH DEFENSE

The improper joinder of Plaintiffs' alleged causes of action violate the procedural and substantive due process rights of Johnson & Johnson under the Constitutions of the United States of America and the applicable state, as well as the applicable Rules of Civil Procedure and the laws of the applicable state.

FIFTEENTH DEFENSE

The improper joinder of Defendants violates the procedural and substantive due process rights of Johnson & Johnson under the Constitutions of the United States of America and the applicable state.

SIXTEENTH DEFENSE

Johnson & Johnson specifically pleads as to Plaintiffs' fraud, deceit by concealment and negligent misrepresentation claims, all affirmative defenses available to Johnson & Johnson under the rules and statutes of California and/or any state whose law is deemed to apply in this case, and under any common law principles of California and/or any state whose law is deemed to apply in this case.

SEVENTEENTH DEFENSE

Johnson & Johnson is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in California or any other state whose law is deemed to apply in this case.

EIGHTEENTH DEFENSE

Plaintiffs' claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and by state and federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the product(s) at issue is/are regulated by the U.S. Food and Drug Administration ("FDA") under the Medical Device Amendments, 21 U.S.C. § 360k, et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulations.

NINETEENTH DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. At all relevant times, however, the product was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360k, et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulations, and Plaintiffs' claims are accordingly barred.

TWENTIETH DEFENSE

Plaintiffs' claims against Johnson & Johnson are expressly and/or impliedly preempted by federal law, including but not limited to the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. See 21 U.S.C. § 301 et seq.; see also Fed. Reg. 3922 (Jan. 24, 2006).

TWENTY-FIRST DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. Plaintiffs' claims nevertheless are barred because the entity responsible for the design, development, manufacture, licensing, marketing, distribution and/or sale of the product complied with all applicable state and federal statutes regarding the product at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that Plaintiffs' claims are not barred, Johnson & Johnson and the entity responsible for the design, development, manufacture, licensing, marketing, distribution and/or sale of the product is entitled to a presumption that the product at issue is/are free from any defect or defective condition as the plans or design for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were adopted.

TWENTY-SECOND DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 et seq., and regulations promulgated thereunder.

TWENTY-THIRD DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. However, Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because the entity responsible for the design, development, manufacture, licensing, marketing, distribution, sale and/or placing the product in the stream of commerce complied with all applicable statutes and with the requirements and regulations of the FDA.

TWENTY-FOURTH DEFENSE

Any claims by Plaintiffs relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Johnson & Johnson to petition the government.

TWENTY-FIFTH DEFENSE

Johnson & Johnson does not manufacture, market, label, promote, distribute or sell any product nor has it ever had possession or control over the product at issue in this action. In any event, Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for medical devices.

TWENTY-SIXTH DEFENSE

Johnson & Johnson does not manufacture, market, label, promote, distribute or sell any product nor has it ever had possession or control over the product at issue in this action. In any event, Plaintiffs cannot state a claim with regard to warnings and labeling

1 for medical devices because the remedy sought by Plaintiffs is subject to the exclusive
2 regulations of FDA.

3 **TWENTY-SEVENTH DEFENSE**

4 Plaintiffs' claim for punitive damages is barred because the product(s) at issue
5 were manufactured and labeled in accordance with the terms of FDA's clearance of the
6 product(s) at issue.

7 **TWENTY-EIGHTH DEFENSE**

8 Plaintiffs' claims are barred in whole or in part by Plaintiffs' failure to assert a
9 safer design for the product(s) at issue.

10 **TWENTY-NINTH DEFENSE**

11 Plaintiffs' claims are barred in whole or in part because the product(s) at issue
12 provided a benefit to users of such product and greatly outweighed any risk created by
13 using such product, any risk could not have been avoided through the use of the highest
14 standards of scientific and technical knowledge available at the time, the benefit provided
15 to users could not be achieved in another manner with less risk, and adequate warnings
16 concerning the risk were provided.

17 **THIRTIETH DEFENSE**

18 Johnson & Johnson made no express or implied representations or warranties of
19 any kind to Plaintiffs, nor did Plaintiffs rely on any representations or warranties made by
20 Johnson & Johnson to others. To the extent Plaintiffs relied upon any representations or
21 warranties, such reliance was unjustified.

22 **THIRTY-FIRST DEFENSE**

23 Any express or implied warranties alleged to have been made by Johnson &
24 Johnson were disclaimed.

25 **THIRTY-SECOND DEFENSE**

26 Johnson & Johnson did not make nor did it breach any express or implied
27 warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely
28 on any theory of breach of warranty, such claims are barred by applicable law, by the

1 lack of privity between Plaintiffs and Johnson & Johnson, and/or by Plaintiffs' failure to
2 give Johnson & Johnson timely notice of the alleged breach of warranty and an
3 opportunity to cure. Johnson & Johnson further specifically pleads as to any breach of
4 warranty claim all affirmative defenses available to Johnson & Johnson under the
5 Uniform Commercial Code, as enacted in California or any other state whose law is
6 deemed to apply in this case, and under the common law principles of California or any
7 other state whose law is deemed to apply in this case.

8 **THIRTY-THIRD DEFENSE**

9 To the extent that any of Plaintiffs' claims can be, or are construed as, alleging a
10 violation of consumer protection laws, Johnson & Johnson specifically pleads all
11 affirmative defenses available to Johnson & Johnson under the rules and statutes of
12 California and/or any state whose law is deemed to apply in this case, and under the
13 common law principles of California and/or any state whose law is deemed to apply in
14 this case.

15 **THIRTY-FOURTH DEFENSE**

16 The injuries and damages allegedly suffered in this action, which are denied, were
17 not foreseeable to Johnson & Johnson given the state of scientific knowledge and state of
18 the art at the time of the alleged injuries. At all times relevant, the product at issue
19 conformed to state-of-the-art specifications and state of scientific knowledge for such
20 product at that time, as well as all applicable statutes and regulations, including those of
21 FDA.

22 **THIRTY-FIFTH DEFENSE**

23 Plaintiffs knowingly and voluntarily assumed any and all risks associated with the
24 use of the product at issue in this case and thus the "last clear chance" and assumption of
25 the risk doctrines bar in whole or in part the damages that Plaintiffs seek to recover
26 herein.

THIRTY-SIXTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the entity responsible for the product acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of the product at issue.

THIRTY-SEVENTH DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. At all relevant times herein, however, the product in question was manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

THIRTY-EIGHTH DEFENSE

Plaintiffs' inadequate warning claims are barred because the alleged risk of which Plaintiffs claim is open, obvious, and/or a matter of common knowledge.

THIRTY-NINTH DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was consistent with and/or exceeded consumer expectations.

FORTIETH DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. Plaintiffs' claims are barred in whole or in part, however, because the product at issue was at all times properly prepared, packaged, and distributed and was not defective or unreasonably dangerous.

FORTY-FIRST DEFENSE

Adequate and complete warnings and instructions were provided with the product at issue. Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. The product at issue, however, was neither defective nor unreasonably dangerous when used according to its Instructions for Use.

FORTY-SECOND DEFENSE

At all relevant times, the warnings and instructions accompanying the product at issue were governed by and conformed with applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the product were presumptively adequate.

FORTY-THIRD DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

FORTY-FOURTH DEFENSE

Johnson & Johnson is not liable to Plaintiffs because the end users of the product(s) at issue, Plaintiff's physician(s), were sophisticated users of the product(s).

FORTY-FIFTH DEFENSE

Johnson & Johnson states that the sole proximate cause of the injuries and/or damages alleged by Plaintiffs was the actions, omissions, or negligence of a person or persons, other than Johnson & Johnson, for whose actions, omissions, or negligence Johnson & Johnson is in no way liable. Plaintiffs are not, therefore, entitled to recover from Johnson & Johnson in this action. As to Plaintiffs or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of Plaintiffs, if any, Johnson & Johnson expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law or policy of California or any other applicable state.

FORTY-SIXTH DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, may have been caused, in whole or in part, by Plaintiffs' own fault, which bars or proportionately reduces Johnson & Johnson's liability, if any, for Plaintiffs' alleged damages.

FORTY-SEVENTH DEFENSE

Plaintiffs voluntarily and unreasonably chose to encounter known dangers.

FORTY-EIGHTH DEFENSE

The liability of Johnson & Johnson, if any, for Plaintiffs' non-economic loss must be apportioned in accordance with the provisions of the law of California or any other state whose law is deemed to apply in this case.

FORTY-NINTH DEFENSE

In the event Johnson & Johnson is held liable to Plaintiffs, which liability is expressly denied, and any other co-defendants are also held liable, Johnson & Johnson is entitled to a percentage contribution of the total liability from said co-defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of the applicable states.

FIFTIETH DEFENSE

There is no causal relationship between Johnson & Johnson's conduct and the injuries and damages alleged by Plaintiffs in the Complaint.

FIFTY-FIRST DEFENSE

At all times mentioned herein, Plaintiffs were negligent, careless and at fault and conducted themselves so as to contribute substantially to their alleged injuries, losses, and damages. Said negligence, carelessness and fault of Plaintiffs bars in whole or in part the damages which Plaintiffs seek to recover herein.

FIFTY-SECOND DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said product.

FIFTY-THIRD DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

FIFTY-FOURTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the product at issue in this case, if any, were caused by the acts or omissions of third parties for which Johnson & Johnson has no legal responsibility. Therefore, Plaintiffs' recovery against Johnson & Johnson, if any, should be reduced pursuant to California Civil Code § 1431.2.

FIFTY-FIFTH DEFENSE

Johnson & Johnson expressly denies any third party engaging in the acts alleged by Plaintiffs was acting as Johnson & Johnson's agent or servant, at the instruction of Johnson & Johnson, or within its control. Therefore, Plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

FIFTY-SIXTH DEFENSE

Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Johnson & Johnson.

FIFTY-SEVENTH DEFENSE

Plaintiffs' claims are or may be barred by their failure to comply with conditions precedent to their right to recover.

FIFTY-EIGHTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of avoidable consequences.

FIFTY-NINTH DEFENSE

The claims of Plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to preserve evidence necessary to the determination of the claims.

SIXTIETH DEFENSE

Plaintiffs' claims against Johnson & Johnson are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if any plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of any such plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than Plaintiff, or, if not disclosed by Plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

SIXTY-FIRST DEFENSE

Some or all of Plaintiffs' claims may be barred by the statutes of limitations, prescription, and/or statutes of repose of California or any other applicable state, including but not limited to California Code of Civil Procedure §§ 335.1, 338(a), 338(d), and 361.

SIXTY-SECOND DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

SIXTY-THIRD DEFENSE

Plaintiffs' alleged damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

SIXTY-FOURTH DEFENSE

The sale, labeling and marketing of the product at issue in this litigation is not, and was not, likely to mislead or deceive the public.

SIXTY-FIFTH DEFENSE

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

SIXTY-SIXTH DEFENSE

Plaintiffs' claims are barred in whole or in part under Section 402A, comments j and k of the Restatement (Second) of Torts, and/or the Restatement (Third) of Torts: Products Liability, Sections 2, 4, and 6 and comments thereto. Adequate warnings and complete warnings were provided to Plaintiffs' prescribing physician, and therefore, the products were not defective or unreasonably dangerous.

SIXTY-SEVENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent Plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised their claims by any means.

SIXTY-EIGHTH DEFENSE

Any recovery by Plaintiffs must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

SIXTY-NINTH DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted for costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

SEVENTIETH DEFENSE

The Complaint fails to state facts sufficient to entitle Plaintiffs to an award of punitive damages.

SEVENTY-FIRST DEFENSE

No act or omission of Johnson & Johnson was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

SEVENTY-SECOND DEFENSE

Plaintiffs' claims for pain and suffering are barred because they violate Johnson & Johnson's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and California or any other applicable state.

SEVENTY-THIRD DEFENSE

The imposition of punitive or exemplary damages would violate Johnson & Johnson's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. They would further violate Johnson & Johnson's rights to the extent that punitive damages awarded to any Plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution as amended; (3) imposed where state law is impermissibly

1 vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a
 2 maximum multiple of compensatory damages or a maximum amount; or (5) imposed on
 3 the basis of anything other than Johnson and Johnson's conduct within the State where
 4 any Plaintiff resides, or in any other way subject Johnson & Johnson to impermissible
 5 multiple punishment for the same alleged wrong.

6 **SEVENTY-FOURTH DEFENSE**

7 Johnson & Johnson specifically incorporates by reference all standards of
 8 limitations regarding the determination and enforceability of punitive damage awards as
 9 applied to the state and federal courts of the applicable states under the Due Process
 10 Clause of the Fourteenth Amendment to the United States Constitution.

11 **SEVENTY-FIFTH DEFENSE**

12 With respect to Plaintiffs' demand for punitive damages, Johnson & Johnson
 13 specifically incorporates by reference all standards of limitations regarding the
 14 determination and enforceability of punitive damage awards that arise under *BMW of*
 15 *North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman*
 16 *Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538
 17 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and its progeny, as
 18 applied by the federal courts of appeals, together with all such standards applicable under
 19 any other state's law.

20 **SEVENTY-SIXTH DEFENSE**

21 Johnson & Johnson asserts the provisions of all applicable statutory caps on
 22 damages of any sort, including punitive, non-economic or exemplary damages, under the
 23 laws of California or any other applicable state.

24 **SEVENTY-SEVENTH DEFENSE**

25 Johnson & Johnson specifically pleads as to Plaintiffs' strict liability claims, all
 26 affirmative defenses available to Johnson & Johnson under the rules and statutes of
 27 California or any other state whose law is deemed to apply in this case, and under any
 28

1 common law principles of California or any other state whose law is deemed to apply in
2 this case.

3 **SEVENTY-EIGHTH DEFENSE**

4 Johnson & Johnson specifically pleads as to Plaintiffs' negligence claims all
5 affirmative defenses available to Johnson & Johnson under the rules and statutes of
6 California or any other state whose law is deemed to apply in this case, and under any
7 common law principles of California or any other state whose law is deemed to apply in
8 this case.

9 **SEVENTY-NINTH DEFENSE**

10 Johnson & Johnson hereby gives notice that it intends to rely upon and incorporate
11 by reference any affirmative defenses that may be asserted by any co-defendant in this
12 lawsuit.

13 **EIGHTIETH DEFENSE**

14 Johnson & Johnson reserves the right to assert any additional defenses and matters
15 in avoidance, which may be disclosed during the course of additional investigation and
16 discovery.

17 **DEMAND FOR JURY TRIAL**

18 Johnson & Johnson demands trial by jury of all issues so triable as a matter of
19 right.

20 WHEREFORE, Defendant Johnson & Johnson prays that:

- 21 (1) Plaintiffs take nothing by reason of the Complaint;
22 (2) The Complaint be dismissed in its entirety and that a Judgment against
23 Plaintiffs and in favor of Johnson & Johnson be entered;
24 (3) Johnson & Johnson be awarded its costs and expenses; and
25 (4) This Court award Johnson & Johnson any other and general or specific relief
26 as this Court may deem just and proper.

27 ///

28 ///

1 DATED: November 7, 2018

TUCKER ELLIS LLP

2
3 By /s/ Joshua J. Wes

4 Joshua J. Wes

Attorneys for Defendants

5 ETHICON, INC. and JOHNSON & JOHNSON
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TUCKER ELLIS LLP
Cleveland ♦ Columbus ♦ Denver ♦ Los Angeles ♦ San Francisco

CERTIFICATE OF SERVICE

I declare that I am a citizen of the United States and a resident of Los Angeles, California or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action. My business address is Tucker Ellis LLP, 515 South Flower Street, Forty-Second Floor, Los Angeles, California 90071-2223.

On **November 7, 2018**, I served the following: **ANSWER AND DEFENSES OF DEFENDANT JOHNSON & JOHNSON TO PLAINTIFFS' FIRST AMENDED COMPLAINT; DEMAND FOR JURY TRIAL** on the interested parties in this action by:

- (X) **ELECTRONICALLY VIA ECF:** the above-entitled document to be served electronically through the United States District Court, Central District ECF website, addressed to all parties appearing on the Court's ECF service list. A copy of the "Filing Receipt" page will be maintained with the original document in our office. () **BY MAIL:** By placing a true copy thereof enclosed in a sealed envelope(s) addressed as above, and placing each
- () **BY MAIL:** By placing a true copy thereof enclosed in a sealed envelope(s) addressed as above, and placing each for collection and mailing on the below indicated day following the ordinary business practices at Tucker Ellis LLP. I certify I am familiar with the ordinary business practices of my place of employment with regard to collection for mailing with the United States Postal Service. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit or mailing affidavit.
- (X) I declare that I am employed in the office of the Bar of this Court at whose direction the service was made.

Executed on **November 7, 2018**, at Los Angeles, California

/s/ Britteena Stafford
Britteena Stafford